claims 16-33 allegedly recite "an additional process step not required in the originally elected invention." Specifically, the additional process step mentioned is accessing and withdrawing. See Final Office Action, page 2, lines 17-18. Applicants traverse.

Newly added claims 22-27 depend from claim 1 and further limit claim 1. Claims 22-27 do not, however, recite "an additional process step not required in the originally elected invention" as asserted in the Final Office Action. Thus, claims 22-27 are not directed to an invention that is independent or distinct from claim 1 according to the reasoning provided. Claims 22-27 should be rejoined.

Moreover, an additional process step in a method does not *per se* render a method a separate patentable invention. Such logic would lead to all dependent claims being separate inventions. The Patent Office has not shown that a search and examination of newly added claims 16-21 and 28-33 (as well as claims 22-27) cannot be made without serious burden. A serious burden may be shown if the Patent Office shows by appropriate explanation either separate classification, separate status in the art or a different field of search. MPEP § 808.02. Because the Office Action has not made such a showing, it is respectfully submitted that claims 16-21 and 28-33 should be rejoined.

Finality of the Rejection

For reasons set forth above, claims 16-33 (or claims 22-27) should be rejoined. Applicant is entitled to a full and fair hearing to clarify issues between applicant and examiner before appeal such that applicant may readily judge the advisability of an

appeal. All outstanding grounds of rejection should be reviewed and grounds relied on in the final rejection should be reiterated. See MPEP 706.07. In the instant application, the Office Action has not addressed claims 16-33 (or claims 22-27) but has nevertheless made the rejection final. Therefore, it is respectfully submitted that the Final Rejection is premature. Withdrawal of the finality of the rejection is respectfully requested.

Rejection of Claims 1 and 6-11 under 35 U.S.C. § 112, first paragraph

Claims 1 and 6-11 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

The Office Action asserts that the specification as originally filed does not provide support for intraductally administering an agent that increases secreted ductal fluid from a breast because the recitation of secreted ductal fluid has neither "literal support in the as-filed specification ..., nor are there specific examples." See Final Office Action page 4, lines 8-9. It is respectfully pointed out that the test for sufficiency of support does not require the subject matter of the claim to be described literally (*i.e.*, using the same terms or *in haec verba*). MPEP § 2163.02 and In re Lukuch, 442 F.2d 967, 58 CCPA 1233, 169 USPQ 795 (1971) (holding that "the invention does not have to be described in *ipsis verbis*"). Nor are specific examples required. In re Long, 151 USPQ 640, 642 (CCPA

1966) (noting that "the absence of a working example ... does not compel the conclusion that a specification does not satisfy the requirements of 35 U.S.C. 112 ...").

The Office Action asserts that there are no specific examples (See Final Office Action, page 4, line 9), but then acknowledges a specific example in the specification of "administration of an agent, namely mannitol, that increases the secretion of retrievable fluid in one or more breast ducts" (See Final Office Action, page 4, lines 14-17). Thus, the Office Action has rebutted its own assertion that there are no specific examples. In any event, specific examples are not required at all to fulfill the written description requirement. Long, 151 USPQ at 642. On the contrary, the written description requirement is satisfied by the patentee's disclosure of "such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." Enzo Biochem, Inc. v. Gen-Probe Inc., No. 01-1230 (Fed. Cir. decided July 15, 2002).

The Office Action cites the specification as disclosing that "ducts are not spontaneously discharging fluid" (page 3, lines 7-13) and as disclosing "intraductal retrieval of ductal fluid from a non-spontaneously discharging duct" (page 5, lines 5-24) and juxtaposes these disclosures with the claimed intraductal retrieval of secreted ductal fluid from a breast duct. See Final Office Action at page 4, line 17 – page 5, line 3. The Office Action thus appears to be asserting that the specification contradicts the claims. However, these passages do not contradict the claimed invention. The cited passages from the disclosure refer to ducts that do not *spontaneously* discharge fluid. "Spontaneously" describes discharge that occurs without external influence (see Merriam

Webster On-Line Dictionary at http://www.m-w.com/cgi-bin/dictionary). Thus, the cited passages refer to breast ducts that do not discharge fluid without external influence (such as without an agent being administered intraductally). The cited passages do not contradict the claimed step of "administering intraductally ... an agent that increases retrievable secreted ductal fluid from a breast duct," as the Office Action implies, because the "agent" constitutes an "external influence" that increases retrievable secreted ductal fluid. Thus, it is immaterial whether the ducts spontaneously (*i.e.*, without external influence) secrete ductal fluid because the claims recite that an external influence is applied.

The Office Action notes that the specification discloses administering an agent "that increases fluid secretion from a breast duct" but concludes that "nowhere does Applicant disclose the intraductal administration of an agent that increases secreted ductal fluid from a breast duct." See Final Office Action at page 5, lines 5-7. It appears that the Office Action concedes the disclosure of an agent that increases fluid secretion in a duct, but nevertheless concludes that there is no support for an agent that increases secreted ductal fluid. It is respectfully submitted that one of skill in the art would clearly find support for an agent that increases secreted ductal fluid in a specification that specifically discloses an agent that increases fluid secretion in a duct. These two grammatical forms express the same concept. Thus one does support the other.

The Final Office Action at page 5, lines 8-11, further elucidates that "claim 1 [as amended] makes it appear that the claimed method is drawn to a method ... wherein the

ductal fluid is already secreted ... vs. a method ... comprising administering ... an agent that increases the secretion of ductal fluid from a breast duct." Claim 1, however, does not recite that the "ductal fluid is already secreted." Claim 1 recites "an agent that increases retrievable secreted ductal fluid from a breast duct." It is axiomatic that secreted ductal fluid in a breast duct is ductal fluid that is the result of secretion into the breast duct. Thus, "an agent that increases retrievable secreted ductal fluid from a breast duct" is abundantly supported in the specification.

The Action asserts that the example provided in the specification of administering mannitol is not sufficient to support "administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast duct" because "this is a matter of written description, not a question of what one of skill in the art would or would not have known," the "material within the four corners of the as-filed specification must lead to the generic concept ... if it does not, the material is new matter," and "declarations and new references cannot demonstrate the possession of a concept after the fact." See Final Office Action at page 5, line 14 – page 6, line 1. Nonetheless, the Office Action has failed to demonstrate that new matter exists.

The specification provides abundant support beyond merely the working example which the PTO points to in isolation. For example, the specification discloses "administering an agent to the patient that increases the retrievable fluid in one or more breast ducts" (page 5, lines 7-8), "administering an agent ... that is capable of increasing ... the fluid volume in the duct" (page 6, lines 21-22), "agent capable of increasing the

amount of retrievable or collectable fluid in the ductal lumen" (page 7, lines 3-4), "whether an agent is capable of increasing ... the amount of collectable fluid (with relation to the amount of fluid infused) in the ductal lumen can be determined by routine tests" (page 8, lines 3-5), "an agent that increases fluid secretion from a breast duct epithelium" (page 9, lines 16-17), and "an agent administered intraductally for the purpose of increasing a ductal fluid reservoir can comprise ... [a Markush group including] mannitol" (page 9, lines 1-2). These generic disclosures must be considered together with the specific example in which mannitol is administered into a breast duct and increased secretion of fluid from the breast duct is observed at page 14, lines 23-25. Long, 115 USPQ at 642 (noting that "the specification as a whole must be considered in determining its sufficiency"). Thus, as a whole, the application discloses an agent that increases retrievable or collectable secreted fluid in a breast duct.

Therefore, claims 1 and 6-11 are allowable.

Rejection of Claims 1 and 8-11 under 35 U.S.C. § 102(e) over Love

Claims 1 and 8-11 were rejected under 35 U.S.C. § 102(e) as being anticipated by Love. This rejection is respectfully traversed.

Claim 1, as amended, recites administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast duct, wherein the agent is selected from the group consisting of a hypotonic solution, a buffered solution, a nonabsorbable biocompatible solution, a protein, a colloid, a sugar, a polymer, mannitol,

sorbitol, glucose, glycerol, sucrose, raffinose, fructose, lactulose, polyethyleneglycol (PEG), maltodextrin, dextran, dextran 70, hydroxyethyl starch, fluid gelatin, a synthetic colloid, an antibody, a binding protein, albumin, a hormone, a natural herb, an extract from a natural herb, silymarin, a surfactant, a growth factor, oxytocin, prolactin, an organic molecule, a muscle relaxant, and a ductal orifice dilator.

Love discloses administration of physiologic saline into a duct of a breast. See col. 3, lines 25-26. Love does not administer any of the agents recited in claim 1 and therefore does not teach each and every aspect of the claim 1 invention.

The Office Action asserts that the "physiologic saline" of Love constitutes any of "a hypotonic solution, a solution having a pH range of human tissue, a buffered solution, or a nonabsorbable biocompatible solution" and, based on this assertion, concludes that Love anticipates claim 1. However, physiologic saline does not constitute any of the alleged substances.

Claim 1 has been amended to delete "a solution having a pH range of human tissue, blood or sera, a solution having a slightly acid pH, a solution having a slightly basic pH." Thus, this portion of the rejection has been rendered moot.

Physiologic saline (also known as "normal saline") is 0.9% saline. See "The Dominance of Sodium" at http://www.vet.ohio-state.edu/docs/fluids/ part9/part9.html (Exhibit A). Normal saline is also referred to as "isotonic sodium chloride". See Ohio State University Medical Center, Department of Nursing, *Health for Life – How to make Normal Saline*, (2002), *at* http://www.acs.ohio-state.edu/units/osuhosp/patedu/Materials/

PDFDocs/ procedure/how-to/makenor.pdf (Exhibit B). As is known in the art, "isotonic" refers to having equal tension, denoting solutions possessing the same osmotic pressure as body tissue/fluids. See Stedman's Medical dictionary definition of "isotonic" (Exhibit C). However, claim 1 recites a "hypotonic solution." "Hypotonic" refers to "having a lesser osmotic pressure". See Stedman's Medical Dictionary definition of "hypotonic" (Exhibit D). Because "physiologic saline" denotes a solution "possessing the same osmotic pressure," it is clearly not the same as a solution "having a lesser osmotic pressure" than body tissue/fluids. Therefore, physiologic saline does not constitute a hypotonic solution.

Stedman's Medical Dictionary defines "buffer" as "a mixture of an acid and its conjugate base, such as H_2CO_3/HCO_3^- that, when present in a solution, reduces any changes in pH that would otherwise occur in the solution when acid or alkali is added to it." See Stedman's Medical Dictionary definition of "buffer" (Exhibit E). See also Brown and Lemay, Chemistry, The Central Science, 2nd edition, Prentice-Hall, Inc., 1981, pages 478-480 (Exhibit F). However, physiologic or normal saline contains salt and water. See Ohio State University Medical Center, Department of Nursing, *Health for Life – How to make Normal Saline*, (2002), *at* http://www.acs.ohio-state.edu/units/osuhosp/patedu/Materials/ PDFDocs/ procedure/how-to/makenor.pdf (Exhibit B) and Brown and Lemay, Chemistry, The Central Science, 2nd Edition, Prentice-Hall, Inc., 1981, pages 349-351 (Exhibit F). Thus, physiologic or normal saline merely contains H_2O, Na^+ and Cl^- but does not contain an acid and its conjugate base (*i.e.*,

HX and a corresponding salt NaX). Therefore, physiologic saline does not constitute a "buffered solution."

Finally, physiologic saline is inherently absorbable. See, *e.g.*, St. Johns County Fire Rescue at http://www.co.st-johns.fl.us/BCC/fire-rescue/phd/NaCl.html (Exhibit G) which states that normal saline has a high sodium content and the "sodium content will cause blood vessels to absorb water, thereby increasing volume in vessels." Therefore, physiologic saline does not constitute a "nonabsorbable biocompatible solution".

It is respectfully submitted that Love does not teach the use of any of the species recited in the claim 1 invention. The rejection should therefore be withdrawn.

Claims 8-11 and 22-27 depend from claim 1 and are allowable over Love for at least the reasons set forth above for claim 1.

Rejection of Claims 1 and 6 under 35 U.S.C. § 103(a) over Ogata

Claims 1 and 6 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Ogata. This rejection is respectfully traversed.

Ogata discloses a method for treating mastitis in which ozone is injected into a breast to expand vessels located at deep regions, promoting discharge to the outside of the body of inflaming products residing at deep regions of the breast. See col. 3, lines 52-64; emphasis added. Inflaming products are described as "infected disease-causing microbes" and "toxins produced by such disease-causing microbes." Col. 4, lines 6-7 and 9-10. The Office Action concludes from this disclosure that ozone expands the milk

ducts and that ozone is "a ductal orifice dilator." However, contrary to the Examiner's assertions, Ogata merely discloses that ozone expands *vessels at deep regions*. See, *e.g.*, col. 3, lines 52-64. The ductal orifice is at the nipple, *i.e.*, at the surface of the breast. Ogata does not teach or suggest a ductal *orifice* dilator. In fact, Ogata does not teach or suggest that ozone has any effect on a ductal orifice at all.

Therefore, it is respectfully submitted that claims 1 and 6 are allowable and the rejection should be withdrawn.

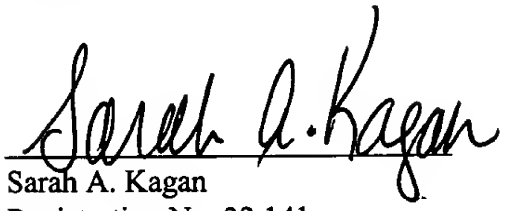
Rejection of claims 1 and 6-11 for obviousness-type double patenting

Claims 1 and 6-11 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 157-165 of USSN 09/907,581. Applicants defer consideration of filing a terminal disclaimer until the determination of allowable subject matter by the Patent Office.

Conclusion

Applicant respectfully submits that the instant application is in condition for allowance. If the Examiner feels, however, that further amendment and/or discussion may be helpful in facilitating prosecution of the case, Applicant respectfully requests a telephone conference with the undersigned attorney of record.

Respectfully submitted,



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Date: February 10, 2003

MARKED UP VERSION OF AMENDMENTS

In the Claims

Please amend claim 1 as follows:

1. (Amended) A method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising:

administering intraductally to the patient an agent that increases retrievable secreted ductal fluid from a breast duct, wherein the agent is selected from the group consisting of a hypotonic solution, a buffered solution, [a solution having a pH range of human tissue, blood or sera, a solution having a slightly acid pH, a solution having a slightly basic pH,] a nonabsorbable biocompatible solution, a protein, a colloid, a sugar, a polymer, mannitol, sorbitol, glucose, glycerol, sucrose, raffinose, fructose, lactulose, polyethyleneglycol (PEG), maltodextrin, dextran, dextran 70, hydroxyethyl starch, fluid gelatin, a synthetic colloid, an antibody, a binding protein, albumin, a hormone, a natural herb, an extract from a natural herb, silymarin, a surfactant, a growth factor, oxytocin, prolactin, an organic molecule, a muscle relaxant, and a ductal orifice dilator.